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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,802

09/22/2005

Teruhiko Oishi

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EXAMINER

FORTUNA, ANA M

ART UNIT

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1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,802	<b>Applicant(s)</b> OISHI, TERUHIKO	
	<b>Examiner</b> Ana M. Fortuna	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/14/05</u>   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-10, 16-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oishi et al (US 6,165,363) in view of Kawata et al (US 5,340,480). Oishi et al discloses an asymmetric membrane with microporous structure and made from a polysulfone/polyvinylpyrrolidone composition resulting in a membrane with a breaking strength of 50 kgf/cm<sup>2</sup> (abstract, column 3, lines 23-48, and column 4, lines 50-65). Claim 1 is directed to a hollow fiber membrane with decreasing pore size from the outer surface to the inner surface. Oishi et al ('363) is directed to forming similar membrane with the opposite asymmetry, e.g. larger pores at the inner surface (Fig. 2). It would have been obvious to one skilled in this art at the time this invention was made to

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produce a membrane with the current claimed properties, and a varying asymmetry in which the larger pore size are provided at the outer hollow fiber membrane surface, e.g by varying inner and outer fluid (coagulation fluid) composition; because varying the percentage of polymer solvent in the inner fluid, and or coagulation fluid, and the coagulation fluid temperature regulates the asymmetry. Kawata et al ('480) teaches a method of making hollow fiber membranes from a composition of polysulfone and polyvinylpyrrolidone, the membrane has the lower pore size at the inner surface, and biocompatibility, forming the membrane with water as inner fluid, to produce the inner smaller pores is suggested (abstract, column 3, lines 45-column 4, line 28; column 4, lines 3-30; column 10, lines 54-41; column 11, lines 34-39). In the later patent, substantially the same percentages of PS and PVP were used as compared to the membrane in the present invention and patent '363 (column 14, example 1, and column 13, lines 10-54). The membrane in Kawata et al has the immunoglobulin retention of less than 90 % as in claim 1 (see column 10, last paragraph bridging column 11). It would have been obvious to one skilled in this art at the time the invention was made to produce a membrane with the strength and pore size allowing protein permeability, such as the membrane of patent'363, with the surface of lower pore size formed at the inner side of the hollow fiber, by following suggestion of patent '480. Since the membrane of patent '363 has substantially the same pore, and are made by the same composition, the skilled in this art can predict that the same rate of permeation of protein can be obtained, when contacting the protein containing solution with the outer side of the

membrane in patent '353, since substantially the difference is that the inner side of patentn'363 is the outer side in the present invention.

As to claim 2, the pores shape is shown in Fig. 2 of patent '363). As to claim 3, substantial large porosity is disclosed in patent '363, for the area of large pore size or sponge (Fig. 1). The membrane ratio of thickness of inner diameter is further disclosed in '363 (see example 4, table 2). The external diameter of claim 5 is not disclosed in the examples of patent '363. Patent '480 suggests making the membrane from the same mixture of polymers with the claimed external diameter (column 13, second paragraph). It would have been obvious to one skilled in this art at the time the invention was made to adjust the membrane thickness, e.g. by reducing polymer concentration in the membrane composition in order to reduce thickness and increase membrane flux, since the thinness the membrane the higher is the permeability.

As to claim 6-10, patent '363 teaches using PVP (polyvinylpyrrolidone) with very high molecular weight, which increases its retention with in the membrane. It would have been obvious to one skilled in the art to use high molecular weight PVP when controlling the membrane formation to obtain smaller pore surface at the inner side of the hollow fiber membrane; for the same amount of PVP of the same molecular weight the same percentage of retention when using a high molecular weight PVP can be predicted by the skilled artisan. The membrane is not limited to a particular process, therefore, claims 8-9 are covered by the membrane structure disclosed above.

Regarding claim 15-25, placing the membrane of patent '363, or the modified membrane of '363 in view of Kawata et al within a conventional dialysis or plasma

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separation system, to perform the blood and protein separation, suggested in patent '480, column 19, example 7.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-15 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7,087,168.

Although the conflicting claims are not identical, they are not patentably distinct from each other because patent '168 is directed to the hollow fiber membrane with the same configuration and made from the same polymeric composition and process. Patent '168 does not claim the membrane strength, however, because the membranes are made from substantially the same composition and process (as comparing the specifications), the strength, protein permeability, and IMG permeabilities appears to be inherent in the membranes of claims 1-10 of the patent (compare process of making steps in patent

'168, column 8, lines 6-column 10, line 11, with process steps in the present invention, steps a-e). The polymer compositions are also the same, therefore the membranes as claimed are the same or obvious variations based on the different suggested compositions and process conditions to make the membrane.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Patent 5,928,774 discloses asymmetric hydrophilic polysulfone membranes with ultrafiltration/microfiltration pore size for protein and immunoglobulin separation. Patent 5,938,929 discloses hydrophilic asymmetric polysulfone for hemodialyzer module; additional references are considered of interest in the art of asymmetric hydrophilic membrane for dialysis treatment. Patent 4,789,733 discloses a process/system of fractionating plasma and treating blood to obtain different components the system includes heating and cooling means, plasma separator, mixer and ultrafiltration membrane.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ana M. Fortuna whose telephone number is (571) 272-1141. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571) 272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ana M Fortuna  
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